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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,125	08/05/2003	Kazunobu Okazaki	Q76820	5755

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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,125	OKAZAKI ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/13/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Non-Final Office Action

Claims 1-11 are pending. No claim is allowed at this time. Amendments are entered.

Summary of this Office Action dated July 23, 2007

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. Double Patenting Rejection
5. 35 USC § 102 Rejection
6. 35 USC § 112 (2) Rejection
7. 35 USC § 103 Rejection
8. Response to Remarks
9. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting Rejection

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 1-3, 5 and 9 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4 of copending Application No. 10/525,385. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims of both applications are drawn to gel composition containing the same components.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-9 rejected under 35 U.S.C. 102(b) as being anticipated by EMOTO, MTSUO (US Patent 6,458,395). The reference discloses all the ingredients as presently claimed. See the entire document especially abstract of the invention, lines 25-30, column 2, lines 4-10, column 3, lines 20-31, 42-54 and 62-67 in column 4, lines 1-9, lines 47-54 and lines 61-64 in column 5, lines 1-12 in column 6examples 1, 2, 4 and 5lines 26-35 in column 11 and claims.

4. The reference discloses a gelatinous food product for supplying balanced nutrition, which is a gel of an emulsified mixture comprising 10 to 50 wt. % of total solid content on a dry weight basis and 50 to 90 wt. % of water, the solid content contains 30 to 90 wt. % of saccharide, 5 to 40 wt. % of lipid, 2 to 60 wt. % of protein, 0.2 to 5 wt. % of organic acid, 0.2 to 5 wt. % of organic acid salt, 0.2 to 5 wt. % of emulsifying agent and 0.2 to 5 wt. % of gelling agent, the food product having a pH of 3.3 to 4 and being a composite of an isoelectric gel of the protein and a heat-soluble gel formed with the gelling agent. The invention also provides a process for preparing the food product. The

gelatinous food product of the invention is particularly suitable for nutrition of patients with dysphagia, since it comprises various nutrients in suitable proportions and has good eating qualities, for instance, ease of swallowing even by patients with dysphagia, owing to the soft jelly form.

The reference discloses that the emulsifying agent for use in the invention can be selected from ones conventionally used in the field of food products. Considering that the food product of the invention is adjusted to an acidic pH, the emulsifying agent preferably has acid resistance. A typical example of such emulsifying agents is pectin. Examples of preferred emulsifying agents other than pectin include egg yolk lecithin, hydrogenated egg yolk lecithin, soybean lecithin, hydrogenated soybean lecithin and like phosholipids; polyoxyethylene monooleate (commercially available as "Tween 80", product of AMR) and like synthetic surfactants; and sucrose fatty acid ester, polyglycerin fatty acid ester and the like.

These emulsifying agents may be used singly or in combination, but usually two or more of them are used in combination. The proportion of the emulsifying agent is preferably about 0.1 to 10%, more preferably about 0.1 to 3%, relative to the amount of the the emulsion to be prepared. The proportion of the emulsifying agent, if calculated as the proportion in the food product of the invention, is about 0.2 to 5%, preferably about 0.5 to 3%, on a dry weight basis.

The protein, one of the essential ingredients of the gelatinous food product of the invention, is selected from ones conventionally used in the field of food products. It is necessary that the protein form an isoelectric gel at the pH of the food product of the invention, i.e., pH 3.3 to 4. Examples of such proteins include gelatin, casein, whey proteins (e.g., lactalbumin), soybean protein and wheat protein; salts of these proteins; decomposition products (acid decomposition products and enzyme decomposition products) of these proteins; extracts of these proteins; concentrates of these proteins; and whole milk powders and skimmed milk powders. The proteins may be used singly or in combination.

The protein is present in the food product of the invention in a proportion of about 2 to 60%, preferably about 10 to 45%, more preferably about 15 to 30% on a dry weight basis. Proportions less than 2% or more than 30% are not preferable, since the resulting food product does not satisfy the requirements for nutritionally balanced food products.

The organic acid and organic acid salt, can be selected from those conventionally used in foods or drinks and capable of adjusting the food product of the invention (gel) to pH 3.3 to 4, more preferably 3.5 to 4. Preferred organic acids include citric acid, tartaric acid, malic acid, succinic acid, ascorbic acid and gluconic acid. These organic acids may be used singly or in combination. It is usually desirable that the organic acid be present in the gelatinous food product of the invention in a proportion of

about 0.2 to 5%, preferably about 0.5 to 3%, on a dry weight basis. Proportions less than 0.2% make it difficult to adjust the food product to pH 3.3 to 4. On the other hand, proportions greatly exceeding 5% impart to the food product too much sourness, which may impair the taste.

Organic acid salts have pH adjusting and buffering action. Examples of organic acid salts include sodium salt, potassium salt and like alkali metal salts of the above organic acids; and calcium salt, magnesium salt and like alkaline earth metal salts of the above organic acids. These organic acid salts may be used either singly or in combination. The organic acid salt is present in the food product of the invention in a proportion of about 0.2 to 5%, preferably about 0.5 to 3%, on a dry weight basis. Proportions less than 0.2% result in insufficient buffering action. Usually, proportions up to 5% can achieve sufficient results.

The gelling agent is preferably selected from ones conventionally used as thickening agents in the field of food products. Examples include pectin, furcelleran, carrageenan, agar, locust been gum, guar gum and arabic gum. They can be used singly or in combination. These gelling agents have suitable gelling ability and gel-stabilizing ability, and thus can impart to the resulting gel desired gel strength and water-releasability, in particular, gel strength and water-releasability such that the gel can be crushed easily in the mouth with the tongue.

It further discloses that xanthan gum, konjak mannan or the like may be used as a part of the gelling agent, when so required. It is desirable that the gelling agent be present in the food product of the invention in a proportion of about 0.2 to 5%, preferably about 0.3 to 2%, on a dry weight basis. If the proportion is less than 0.2%, the obtained food product has insufficient gel strength. On the other hand, if the proportion greatly exceeds 5%, the obtained gel is too firm, failing to provide the contemplated food product for patients with dysphagia.

For fruit juices see lines 44-54 in column 5, for vitamin D seine 8 in column 6, for calcium see 55-64 in column 5.

The PH disclosed is between 3.3 to 4.0

Claim 1 and 10 of the references is as follows.

Claim 1. A gelatinous food product for supplying balanced nutrition, which is a gel of an emulsified mixture comprising 10 to 50 wt. % of the combined amount of the ingredients listed below, on a dry weight basis, and 50 to 90 wt. % of water, the gel having a pH of 3.3 to 4, and being a composite of an isoelectric gel of the protein and a heat-soluble gel formed with a gelling agent.

Claim 10. A process according to claim 8 wherein the gelling agent is at least one member selected from the group consisting of pectin, furcelleran, carrageenan, agar, locust bean gum, guar gum and arabic gum.

As is clear all the ingredients and proportions are anticipated by the reference.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 5 are duplicate claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMOTO, MITSUO (US Patent 6,458, 395) and CHRISTOPHER et al. (Experimental Biol. 2—3:Meeting abstract).

The references teach a composition and process of making a nutritional supplement using whey protein, hydrogenated soybean, organic acid vitamin D and various other ingredients, which embraces presently claimed invention.

EMOTO teahes when specific amounts of lipid, saccharide, organic acid, organic acid salt, emulsifying agent and gelling agent are added to a protein so as to obtain an emulsion having an acidic pH equal or close to the isoelectric point of the protein, a composite of an isoelectric gel of the protein and a gel formed with the gelling agent is obtained, which is soft and homogeneous and capable of being swallowed without chewing..

The reference teaches a gel of an emulsified mixture comprising 10 to 50 wt. % of the combined amount of the ingredients listed below (on a dry weight basis) and 50 to 90 wt. % of water, and which has a **pH of 3.3 to 4**, and which is a composite of an isoelectric gel of the protein and a heat-soluble gel formed with the gelling agent. good storage stability because of its pH of 3.3 to 4, preferably 3.5 to 4. Moreover, in spite of the acidic pH, the food product of the invention is free from grains of **coagulated protein,** and has smoothness and homogeneity that impart good eating qualities and textural properties to the food product.

The ingredients and proportions of the gelatinous food product of the invention are described in the references.

The gelatinous food product of the invention has good eating qualities and can be safely eaten by patients with dysphagia associated with various diseases or

following surgical operations, the food product being capable of supplying well balanced nutrition. Further, the food product of the invention is suitable for not only the patients but also healthy people, for example, athletes who need to obtain nutrition quickly during training or competition.

The protein, one of the essential ingredients of the gelatinous food product of the invention, is selected from ones conventionally used in the field of food products. It is necessary that the protein form an isoelectric gel at the pH of the food product of the invention, i.e., pH 3.3 to 4. Examples of such proteins include gelatin, casein, whey proteins (e.g., lactalbumin), soybean protein and wheat protein; salts of these proteins; decomposition products (acid decomposition products and enzyme decomposition products) of these proteins; extracts of these proteins; concentrates of these proteins; and whole milk powders and skimmed milk powders. The proteins may be used singly or in combination.

The protein is present in the food product of the invention in a proportion of about 2 to 60%, preferably about 10 to 45%, more preferably about 15 to 30% on a dry weight basis. Proportions less than 2% or more than 30% are not preferable, since the resulting food product does not satisfy the requirements for nutritionally balanced food products.

The reference also teaches organic acids and vitamins including vitamin D as ingredients (lines 1-20 and 55-68 in column 5, lines 1-12 in column 6). See examples and claims.

EMOTO does not teach increasing plasma volume.

CHRISTOPHER teaches that plasma volume increases after exercise. Claims 10 and 11 are drawn to method of increasing plasma volume. The increase in plasma volume after the exercise is inherent because same gel composition as food is taken by the athelete as claimed and after exercise plasma volume is expected to increase.

It would have been obvious to one skilled in the art at the time of invention to prepare a nutritional supplement containing a protein which does not coagulate at 3.3 to PH 4 (whey protein, as in the disclosure of the present invention) and vitamin D and other ingredients in the form of a gel because prior art teaches the nutritional supplement and process of making them in the form of a gel. Motivation has been provided by the reference. Since no new concept and/or improvement were noted therefore presently claimed invention has been considered obvious over the prior art of record.

The proportions and percentage are taught by the references. Even if these were not in the ranges court has decided that normally, change in temperature, concentration, or both, is not a patentable modification; however, such changes may impart patentability to a process if the ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from results of prior art; such

ranges are termed "critical" ranges, and applicant has burden of proving such criticality; even though applicant's modification results in great improvement and utility over prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art; more particularly, where the general conditions of the claim are disclosed in the prior art, it is not inventive to discover optimum or workable ranges by routine experimentation. In re Aller et al. 105 USPQ 233. The formulation as gel would have been obvious to one who is familiar with the art.

It is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 U.S.P.Q. 33 (C.C.P.A. 1937). In re Russell, 439 F.2d 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971).

Since no criticality and/or unexpected results are seen presently claimed invention is considered obvious over the prior art of record.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

- Claims are amended therefore rejection under 112 (1) is withdrawn.
- Rejection over KITABATAKE et al. and NAKAGAWA et al. is withdrawn because arguments are found persuasive.

- The reference cited in specification must be presented in IDS. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER